Effect of Psyllium and Flaxseed on glucose, lipids, and constipation in patients with type 2 diabetes and chronic constipation

Protocol summary

Study aim
To compare effects of psyllium and flaxseed supplement versus those who received a placebo on glycemic and lipid control and constipation in patients with type 2 diabetes (T2D) and chronic constipation.

Design
single-blinded, randomized controlled trial. 90 patients with T2D and chronic constipation will receive either 10 grams of psyllium mixed in biscuit twice per day or 10 grams of flaxseed mixed in biscuit twice per day or placebo biscuit for 12 weeks. Fasting plasma glucose, glycosylated hemoglobin (HbA1c), and lipid profile, as well as the constipation score, will be determined at the beginning and end of 4, 8, and 12-week period. constipation will be a score on the ROME III rating scale.

Settings and conduct
This is a single-blinded, randomized placebo-control trial of 90 consecutive patients with T2D and symptoms of chronic constipation attending outpatient clinics in Isfahan Endocrine and Metabolism Research Center.

Participants/Inclusion and exclusion criteria
Patients will be included if they had a bowel movement frequency of < 3/week during the past three months; age ≥30 years and diabetes duration > 1 year. Patients will be excluded from the study if they had type 1 diabetes, weight loss, lipid-lowering drug treatment, fiber supplementation, anorectal problems, abdominal pain, and history of opioid use in the last 48 h, any other factors which would interfere with constipation assessment and management, or pre-existing severe cardiac, endocrinological, hematological, hepatic, renal, metabolic, neurological or psychiatric disorders. Pregnant or nursing women will be excluded. Non-compliant patients during baseline or treatment phases as evaluated by taking <75% of either of the test articles during a one-week period throughout the course of the study will be excluded from the evaluable patient data analysis.

Intervention groups
Participants in the control group will be received psyllium and sugar-free orange-flavored maltodextrin cookies for 12 weeks as placebo. The psyllium group will be received 10 g psyllium premixed in a sugar-free orange-flavored maltodextrin cookies twice per day for 12 weeks. The flaxseed group will be received 10 g flaxseed premixed in a sugar-free orange-flavored maltodextrin cookies twice per day for 12 weeks.

Main outcome variables
Primary outcome measures will be included analysis of numerical values of constipation intensity. Secondary outcome measures will be included analysis of the body weight, glycemic and lipid control.

General information
Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20110416006202N2
Registration date: 2017-12-29, 1396/10/08
Registration timing: registered_while_recruiting

Registrant information
Name
Mohsen Janghorbani
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Recruitment status
Recruitment complete
Funding source
Isfahan Endocrine and Metabolism Research Center

Expected recruitment start date
2017-09-23, 1396/07/01
Expected recruitment end date
2018-02-20, 1396/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Psyllium and Flaxseed on glucose, lipids, and constipation in patients with type 2 diabetes and chronic constipation

Public title
Effect of Psyllium and Flaxseed on glucose, lipids, and constipation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients were included if they had type 2 diabetes. A bowel movement frequency of < 3/week during the past three months.

Exclusion criteria:
Patients were excluded from the study if they had weight loss, rectal bleeding abdominal pain history of opioid use in the last 48 h pre-existing severe cardiac endocrinological hematological hepatic renal metabolic neurological or psychiatric disorders Pregnant or nursing women will be excluded Non-compliant patients during baseline or treatment phases as evaluated by taking <75% of either of the test articles during a one-week period throughout the course of the study will be excluded from the evaluable patient data analysis.

Age
From 30 years old to 75 years old

Gender
Both

Phase
2-3

Groups that have been masked
- Participant
- Data analyser

Sample size
Target sample size: 90

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomized according to a preexisting list produced by a computer program that differed from a random number generator only in that it assigned equal numbers of patients to each treatment group, and the group assignments were concealed in an opaque sealed envelope.

Blinding (investigator's opinion)
Single blinded

Blinding description
The trial is single-blinded in that patients will be blind to the treatment. Masking of the two treatments was preserved by creating cookies that looked, tasted, and textured identically. The differences in taste were minimal because the prominent flavor was that of the orange-flavor in which cookies was mixed. Because each participant received only one kind of cookie, the participant had no way to compare their cookie with the other.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences ethic committee
Street address
Hezarjerib
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Province
Isfehan
Postal code
8184935331
Approval date
2015-04-21, 1394/02/01
Ethics committee reference number
IR.MUI.REC.1396.3.464

Health conditions studied

1
Description of health condition studied
Constipation
ICD-10 code
K59.0
ICD-10 code description
Constipation

2
Description of health condition studied
Cholesterol and lipid metabolism
ICD-10 code
E78.7
ICD-10 code description
Disorders of bile acid and cholesterol metabolism
Description of health condition studied

**Elevated blood glucose**

**ICD-10 code**
R73

**ICD-10 code description**
Elevated blood glucose level

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**BMI**

**ICD-10 code**
Z68

**ICD-10 code description**
Body mass index [BMI]

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Primary outcomes

1. **Description**
   constipation intensity

   **Timepoint**
   Beginning, 4, 8, 12 week after intervention

   **Method of measurement**
   ROME III

2. **Description**
   body weight.

   **Timepoint**
   Beginning, 4, 8, 12 week after intervention

   **Method of measurement**
   Body mass index and body weight.

3. **Description**
   lipids .

   **Timepoint**
   Beginning, 4, 8, 12 week after intervention

   **Method of measurement**
   Routine measurement of total cholesterol, triglyceride, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol,

4. **Description**
   fasting plasma glucose .

   **Timepoint**
   Beginning, 4, 8, 12 week after intervention

   **Method of measurement**
   Oxidase method.

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Secondary outcomes

empty

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**Intervention groups**

1. **Description**
   Intervention 2: 10 grams of psyllium mixed in cookies twice per day for 12 weeks. Kamvar Co., Isfahan, Iran

   **Category**
   Treatment - Drugs

2. **Description**
   Intervention 1: 10 grams of faxseed mixed in cookies twice per day for 12 weeks. Kamvar Co., Isfahan, Iran

   **Category**
   Treatment - Drugs

3. **Description**
   Control group: Participants in the control group will be received psyllium, faxseed and sugar-free orange-flavored maltodextrin cookies for 12 weeks as placebo. Kamvar Co., Isfahan, Iran

   **Category**
   Placebo

---

Recruitment centers

1. **Recruitment center**
   **Name of recruitment center**
   Isfahan Endocrine and Metabolism Research Center

   **Full name of responsible person**
   Ashraf Aminorroaya

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Sponsors / Funding sources

1. **Sponsor**
   **Name of organization / entity**
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   **Full name of responsible person**
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

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Sharing plan
Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to

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make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
Yes - There is a plan to make this available

**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Yes - There is a plan to make this available

**Title and more details about the data/document**
Publish paper

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When the data will become available and for how long
starting in March 2018

To whom data/document is available
both people in academic and business

Under which criteria data/document could be used
undecided yet

From where data/document is obtainable
From M. Janghorbani janghorbani@yahoo.com

What processes are involved for a request to access data/document
Contact with the corresponding person.

Comments